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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,373	02/07/2006	Nobuaki Sumiyoshi	2005_1741A	3630

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WASHINGTON, DC 20006-1021

EXAMINER
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KASSA, TIGABU

ART UNIT	PAPER NUMBER
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1619

MAIL DATE	DELIVERY MODE
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01/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,373	<b>Applicant(s)</b> SUMIYOSHI ET AL.	
	<b>Examiner</b> TIGABU KASSA	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/23/08 and 12/06/05</u> .                                   | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Election/Restrictions*

**Claims 1-15 are pending. Claims 1-15 are under consideration in the instant office action.**

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d).

### *Information Disclosure Statement*

The information disclosure statement (IDSs) submitted on 01/23/08 and 12/06/08 is noted and the submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-2, 6-8, and 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Veech (US Patent 5,200,200 IDS reference).**

Instant claim 1 recites an aseptic preparation contained in two or more separate chambers which contains at least one medicinal ingredient wherein the ingredients are divided into the separate chambers. Instant claim 2 recites the preparation of claim 1 wherein the chambers are either within one container or separated between chambers.

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Instant claim 6 recites a preparation according to claim 1 wherein each solution of the medicinal ingredient has a maximum potassium ion concentration of 40 meq/L. Instant claim 7 recites the preparation according to claim 6 wherein the medicinal ingredient(s) is a potassium salt. Instant claim 8 recites the preparation according to claim 1 wherein the container is plastic and the chambers are separated by a partition wall which is opened upon use for aseptic mixing of the ingredients. Instant claim 10 recites the preparation according to claim 2 wherein the solution divided into the chambers has a max potassium ion concentration of 40 meq/L. Instant claim 11 recites the preparation according to claim 2 wherein the container is plastic and the chambers are separated by a partition wall which is opened upon use for aseptic mixing of the ingredients. Instant claim 15 recites the preparation according to claim 6 wherein the plastic container has a plurality of chambers separated by a partition wall which is opened upon use for aseptic mixing of the ingredients.

Veech teaches the packaging of separate component compositions in individual chambers within a container wherein a passageway can be opened between the chambers just prior to use (abstract). The container is designed such that the chambers are internally communicable while the container is still sealed so that final solution preparation is achieved under sterile conditions before use (column 2, lines 40-43). The chambers can contain, for example, redox active therapeutic aqueous compositions (column 2, lines 53-55) which is equivalent at least one medicinal ingredient. Exemplary solutions are disclosed by Veech in column 6, lines 11-39. Each of these solutions contains potassium ions up to 5 mM/L which is equivalent to 5 meq/L of potassium ions. The first composition (column 6, lines 16-24) contains sodium and chloride ions. The second

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solution (column 6, lines 30-39) contains sodium, chloride and bicarbonate ions and also glucose.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

**Claims 1, 3-5, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US Patent 5,200,200, IDS reference) in view of Nakamura et al (US Patent 6867193).**

*Applicant Claims*

Instant claim 1 recites an aseptic preparation contained in two or more separate chambers which contains at least one medicinal ingredient wherein the ingredients are divided into the separate chambers. Instant claim 3 recites the preparation of claim 1 wherein the osmotic pressure ratio between the two chambers is 0.5-8. Instant claim 4 recites the preparation of claim 3 wherein a bicarbonate salt and sugar are accommodated in the chambers. Instant claim 5 recites the preparation of claim 3 wherein the medicinal ingredient(s) is/are sodium salt or/and a sugar. Instant claim 12 recites the preparation according to claim 3 wherein the container is plastic and the chambers are separated by a partition wall which is opened upon use for aseptic mixing of the ingredients. Instant claim 13 recites the preparation according to claim 4 wherein the container is plastic and the chambers are separated by a partition wall which is opened upon use for aseptic mixing of the ingredients. Instant claim 14 recites the preparation according to claim 5 wherein the container is plastic and the chambers are separated by a partition wall which is opened upon use for aseptic mixing of the ingredients.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Veech are disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

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Veech does not teach an osmotic pressure ratio of 0.5-8. This deficiency is cured by the teaching of Nakamura et al.

Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). In example 1, the osmotic pressure ratio between the amino acid and the albumin containing solutions was 2.8-3.3 (column 5, lines 8-14).

***Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to ensure that the osmotic pressure ratio between the two solutions because Nakamura et al. teach an osmotic pressure ratio of 2.8-3.3 between two solutions of a medicinal preparation contained in adjacent chambers until mixing just prior to use. An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because the osmolality of medicinal preparations is important for the safety and efficacy of the preparation. Moreover, the instant specification points out that the administration of solutions of the incorrect osmolality due to medical error is already a well known medical problem. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Veech and Nakamura et al. teach medicinal preparations contained in two or more adjacent chambers which are mixed just prior to use.

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Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### **Conclusion**

Claims 1-15 are pending. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

01/16/09

/PORFIRIO NAZARIO GONZALEZ/  
Primary Examiner, Art Unit 1621



